SOP#: ADCR-2	**CCR Participant Registration & Status Updates**
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NCI Clinical Director Signature: William L. Dahut -S

Digitally signed by William L. Dahut -S
Date: 2020.10.08 09:44:36 -04'00'

POLICY

Research participants who sign an informed consent document for any Center for Cancer Research (CCR) protocol, including multi-site studies, are considered enrolled in that clinical research study when both the participant and the Investigator have signed the consent document. Participant registration and status upate is completed via online Patient Registration/Status Update Form OR the Patient Registration and Enrollment System (PRES) and is managed by the NCI Central Registration Office (CRO).

Participants that sign an informed consent document for a research protocol at the CCR are required to be registered within **24 hours** of the participant signing the consent document. If written consent is obtained via telephone, registration is required within 24 hours of the receipt of the signed consent document. Registration will be completed by the CCR Study Coordinator.

Participants **MUST** have a Medical Record Number (MRN) prior to registration and this number **MUST** be included on the registration form. See SOP ADCR-13 *Clinical Center External Location Registration* for more information on how to obtain an MRN for participants who may not be coming to the Clinical Center (CC).

If the protocol requires registration via OPEN, IRSW, or other sponsor-specific system, the external registration process MUST occur prior to CRO registration/PRES; this will allow the CRO/PRES to obtain the accurate unique study-specific subject ID assigned by the external system.

Participants must be registered for each protocol for which a consent is signed.

For treatment protocols, treatment should begin within 72 hours (or three business days) of participant registration, unless otherwise specified in protocol.

When the participant's status changed to off treatment and/or off study, the status change needs to be entered within **5 business days** of the study team becoming aware of the change.

For multi-site protocols when CCR is the Coordinating Center see SOP: MI-3.

PURPOSE

To describe the steps required to register a research participant on a CCR protocol using the online Patient Registration/Status Update Form OR the Patient Registration and Enrollment System (PRES).

RESOURCES

- Center for Cancer Research Standard Operating Procedures
  - ADCR-13: *Clinical Center External Location Registration*
  - MI-3: *Multi-Institutional: Participating Site Participant Registration & Status Update*
- NCI Central Registration Office Help Line 240-760-6080
  - CRO email (in Global "NCI Central Registration Office")
  - CRO hours of operations: 8:30am-5:00pm, Monday-Friday, excluding federal holidays.
- Interim CCR Study Subject Registration Form
- Interim CCR Study Subject Off-treatment/Off-study Form
- Patient Registration and Enrollment System (PRES)
  - PRES User Guide
  - PRES Login

PROCEDURE: PARTICIPANT REGISTRATION USING THE ONLINE PATIENT REGISTRATION FORM

1. Study Coordinator completes and submits the online Interim CCR Study Subject Registration Form.
2. CRO will be immediately be notified when a new form has been submitted.
3. CRO will contact the Registrar if more information is needed.
4. If an incorrect entry was realized after the submission (e.g., incorrect protocol number), the RNC should send the correction via encrypted email to the CRO (in Global "NCI Central Registration Office").
5. CRO will assign the participant to the appropriate protocol in CRIS.
6. CRO will complete the Verification of Registration Form (VRF) and send to Registrar and the Data Management Team. Should the Registrar have an out of office, the form will be forwarded to that team member covering.
    a. Randomized Studies: The randomized treatment assignment will be provided on the Verification of Registration form.
    b. Masked studies: The sequence number will be provided on the Verification of Registration form.

PROCEDURE: PARTICIPANT REGISTRATION USING THE PATIENT REGISTRATION AND ENROLLMENT SYSTEM (PRES)

1. Training is required prior to using PRES.
2. Refer to the PRES instruction manual for the appropriate steps.

PROCEDURE: PARTICIPANT STATUS UPDATES

1. Study Coordinator completes and submits the online Interim CCR Study Subject Off-treatment/Off-study Form.
2. CRO will be immediately be notified when a new form has been submitted.
3. CRO will contact the registrar if more information is needed.
4. If an incorrect entry was realized after the submission (e.g., incorrect reason off study), the Registrar should send the correct via encrypted email to the CRO (in Global "NCI Central Registration Office").
5. CRO will acknowledge receipt of the update.